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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,794	07/15/2003	Jeff J. Staggs		1100

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06/01/2005

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,794

Applicant(s)

STAGGS, JEFF J.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 1 and 4-6 are presented for examination.

Claims 2 and 3 are considered to be cancelled since the applicant's amendment to the claims is withdrawn before an examination of the application.

Applicant's preliminary amendment filed February 28, 2005 has been received and entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bacteria infections caused by *Staph aureus* with the administration of black pepper, does not reasonably provide enablement for treating infectious diseases, and bacterial infections caused by various Gram-negative and Gram-positive bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary

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- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to methods for treating infectious diseases, and bacterial infections and cellulitis caused by drug-resistant strains of bacteria.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the administration of pepper is effective against various Gram-negative and Gram-positive bacteria in order to treat infectious diseases caused by drug-resistant strains of bacteria and bacterial infections.

The breadth of the claims

The claims are very broad and inclusive to all types of bacterial, gram-negative and gram-positive.

The amount of direction or guidance provided and the presence or absence of working examples

One working example shows a black pepper lotion was administered to a woman with a bacterial infection caused by a drug-resistant strain of *Staph aureus* developed in the surgical incision from a caesarian section.

No examples showing what specific bacteria were eradicated that causes various infectious diseases, and various bacterial infections that includes necrotizing fasciitis (flesh eating disease).

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the antibacterial activity of pepper is effective against all gram-negative and gram-positive bacterial. The level of experimentation needed to determine the antibacterial activity of pepper would be able to treat bacterial infections caused by various or a number of bacteria is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1 and 4-6 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 6, the phrase "includes" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al., "Antibacterial and antitumor activities of piperine from black pepper", Kenkyu Kiyo-Tokyo Kasei Daigaku, 1985, Vol. 25, pp. 201-203 or Dorman et al., "Antimicrobial agents from plants: antibacterial activity of plant volatile oils", Journal of Applied Microbiology, 2000, Vol. 88, No. 2, pp. 308-316.

Yamaguchi et al. teaches extraction of piperine from black pepper possess antibacterial activity against bacteria strains, *Pseudomonas aeruginosa* and *Alcaligenes F2518* (See the enclosed abstract).

Dorman et al. teach the volatile oils of black pepper (*Piper nigrum* L.) were test against twenty-five bacterial strains (page 309, under Bacterial strains) nine Gram-positive and 16 Gram-negative and the results were listed in Table 1. Note the results in Table 1 (page 310) shows the volatile oils of black pepper were effective against various bacteria.

Clearly, both references teach the extractions from black pepper are effective against a wide spectrum of bacteria. Thus, to treat infectious diseases caused by drug-resistant strains of bacteria and treat bacterial infections broadly as suggested by the applicant with the administration of an antibacterial agent obtained from pepper are clearly inherent. Applicant's instant invention is anticipated by the cited reference, therefore, the instant invention is unpatentable.

Claims 1 and 4 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al., "Antibacterial and antitumor activities of piperine from black pepper", Kenkyu Kiyo-Tokyo Kasei Daigaku, 1985, Vol. 25, pp. 201-203 or Dorman et al., "Antimicrobial agents from plants: antibacterial activity of plant volatile oils", Journal of Applied Microbiology, 2000, Vol. 88, No. 2, pp. 308-316.

The two cited references, Yamaguchi et al. and Dorman et al., were discussed individually above supra for the use of extractions and volatile oils of black pepper possess antibacterial activity against various Gram-negative and Gram-positive bacteria.

The instant invention differs from the cited references in that the cited references do not teach the extractions or volatile oils of black pepper were effective to treat cellulitis in a human or necrotizing fasciitis. However, one skilled in the art would have assumed the administration of extractions or volatile oils of black pepper would be effective to treat cellulitis since cellulitis is an acute inflammation of the connective tissue of the skin caused by infection caused by staphylococcus, streptococcus or other bacteria, the administration of extractions or volatile oils of black pepper would be eradicate the bacteria that caused cellulitis or necrotizing fasciitis in the absence of evidence to the contrary.

Claims 5 and 6 are not allowed.

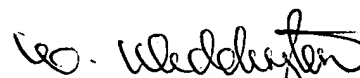
The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
May 26, 2005